

EXHIBIT E

DOCKET NO.: 107071.001406
Application No.: 18/646,329
Office Action Dated: October 11, 2024

PATENT

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. **(Original)** A method of treating cancer in a human in need thereof comprising providing a liquid bendamustine-containing composition comprising
bendamustine, or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is from about 20 mg/mL to about 60 mg/mL,
a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and
a stabilizing amount of an antioxidant
wherein the total impurities in the liquid bendamustine-containing composition resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5° C to about 25° C;
diluting the liquid bendamustine containing composition; and
intravenously administering the diluted composition to the human.
2. **(Original)** The method of claim 1, wherein the liquid bendamustine containing composition is diluted with about 50 mL of a diluent.
3. **(Original)** The method of claim 1, wherein the concentration of bendamustine in the liquid bendamustine-containing compositions is about 25 mg/ml.
4. **(Original)** The method of claim 1, wherein the concentration of bendamustine in the liquid bendamustine-containing composition is 25 mg/ml.
5. **(Original)** The method of claim 1, wherein the liquid bendamustine-containing composition includes 100 mg of bendamustine at a concentration of 25 mg/mL.

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6. **(Original)** The method of claim 1, wherein the antioxidant is monothioglycerol.
7. **(Original)** The method of claim 1, wherein the antioxidant in the liquid bendamustine containing composition is monothioglycerol in a concentration of about 5 mg/mL.
8. **(Original)** The method of claim 1, wherein the liquid bendamustine-containing composition is stable for at least about 15 months at 5° C or for at least about 15 months at 25° C, prior to dilution.
9. **(Original)** The method of claim 1, wherein the liquid bendamustine-containing composition further comprises ethanol.
10. **(Original)** The method of claim 1, wherein the liquid bendamustine-containing composition is packaged in a sterile vial.
11. **(Original)** A method of treating cancer in a human in need thereof comprising providing a liquid bendamustine-containing composition packaged in a sterile vial and comprising
 - 100 mg of bendamustine, or a pharmaceutically acceptable salt thereof, at a concentration of about 25 mg/mL;
 - a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and
 - a stabilizing amount of an antioxidant that is monothioglycerol;wherein the total impurities in the liquid bendamustine-containing composition resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5° C or for at least about 15 months at 25° C;
diluting the liquid bendamustine containing composition with about 50 mL of a diluent;

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and intravenously administering the diluted composition to the human.

12. **(Original)** The method of claim 11, wherein the liquid bendamustine-containing composition comprises 100 mg of bendamustine, or a pharmaceutically acceptable salt thereof, at a concentration of 25 mg/mL.

13. **(Original)** The method of claim 11, wherein the liquid bendamustine-containing composition further comprises ethanol.

14. **(Original)** The method of claim 11, wherein the liquid bendamustine containing composition is diluted with about 50 mL of a diluent.